

**Maryland Board of Pharmacy  
Public Board Meeting**

**Minutes  
September 18, 2019**

<b>Name</b>	<b>Title</b>	<b>Present</b>	<b>Absent</b>
Ashby, D.	Commissioner		
Bouyoukas, E	Commissioner		
Evans, K.	Commissioner		
Hardesty, J.	Commissioner/Treasurer		
Laws Jr, A.	Commissioner		
Leikach, N.	Commissioner		
Morgan, K.	Commissioner/President		
Oliver, B	Commissioner		
Rusinko, K.	Commissioner		
Yankellow, E.	Commissioner		
Bethman, L.	Board Counsel		
Felter, B.	Board Counsel		
Speights-Napata, D.	Executive Director		
Fields, E.	Deputy Director /Operations		
James, D.	Licensing Manager		
Leak, T.	Compliance Director		
Clark, B.	Legislative Liaison		
Chew, C.	Management Associate		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	
<b>I. Executive Committee Report(s)</b>	<b>K. Morgan, Board President</b>	<p><i>Members of the Board with a conflict of interest relating to any item on the agenda are advised to notify the Board at this time or when the issue is addressed in the agenda.</i></p> <ol style="list-style-type: none"> <li><b>1. Call to Order 9:32 AM</b></li> <li><b>2. Sign-in Introduction and of meeting attendees –</b> <i>(Please indicate on sign-in sheet if you are requesting CE Units for attendance)</i></li> <li><b>3. Distribution of Agenda and packet materials</b></li> <li><b>4. Review and approve August 2019 Public Meeting Minutes</b></li> </ol>	<p>Motion by D. Ashby approval of August 2019 Public Meeting minutes 2<sup>nd</sup> by E. Yankellow</p>	<p>The Board voted to approve this motion</p>
<b>II. A. Executive Director Report</b>	<b>D. Speights-Napata, Executive Director</b>	<ol style="list-style-type: none"> <li><b>1. Staffing and Training Update</b></li> <li><b>2. Board Vacancies</b></li> </ol>	<p><b>1a. D. Speights-Napata introduced Sabrina Mercer as new Licensing Specialist</b></p> <p><b>b. Position posted on state website for full time Investigative Supervisor</b></p> <p><b>2. Currently have 3 board meeting vacancies. One At-Large Representative, one Independent Pharmacist, one Consumer Representative will become vacant next month</b></p>	

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		<b>3. Upcoming Meetings</b>  <b>4. CE Breakfast Reminder</b>  <b>5. National Boards of Pharmacy MPJE Multi-State Question Review Meeting--Karla Evans</b>	<b>3. NABP district meeting- Board President K. Morgan, Commissioner N. Leikach and Executive Director D. Speights-Napata will attend.</b>  <b>4. Registration is open and available on website. Close to 300 licensees have signed up.</b>  <b>5. D. Speights-Napata turned over to K. Evans. K. Evans and K. Rusinko attended the meeting. MPJE now has a pre-test that they offer on their website for last year pharmacy students and graduates.</b>	
<b>B. Operations</b>	<b>E. Fields, Deputy Director/ Operations</b>	<b>1. Procurement and Budget Updates</b> a: <b>August 2019 Financial Statements</b>  <b>2. Management Information Systems (MIS) Unit Updates</b> None	Same as August finances  Starting with November renewals, 10% of vaccination licenses will be selected for audit	
<b>C. Licensing</b>	<b>E. Bouyoukas, Commissioner</b>	<b>1. Unit Updates</b> <b>2. Monthly Statistics</b>	<b>Numbers reflect most updated</b>	

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			License Type	New	Renewed	Reinstated	Total	
			Distributor	11	27	0	1,314	
			Pharmacy	8	0	0	2,052	
			Pharmacist	117	459	0	12,271	
			Vaccination	69	81	0	4,769	
			Pharmacy Intern - Graduate	8	0	0	50	
			Pharmacy Intern - Student	22	10	0	796	
			Pharmacy Technician	120	355	2	9,894	
			Pharmacy Technician-Student	2	0	1	28	
			TOTAL	357	932	3	31,257	
D. Compliance	T. Leak, Compliance Director	1. Unit Updates 2. Monthly Statistics Complaints & Investigations:  New Complaints - 22  • Employee Pilferage – 1					Numbers reflect most updated	

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		<ul style="list-style-type: none"><li>• Fraud – 1</li><li>• Dispensing Error – 1</li><li>• Refusal to Fill – 3</li><li>• Inspection Issues – 12</li><li>• Expired/Invalid CPR Certification – 4</li></ul> <p>Resolved (Including Carryover) – 42 Actions within Goal – 35/42 Final disciplinary actions taken – 14 Summary Actions Taken – 1 Average days to complete – 60</p> <p><b>Inspections:</b></p> <p>Total - 132 Annual Inspections - 123 Opening Inspections - 3 Closing Inspections - 5 Relocation/Change of Ownership Inspections - 1 Board Special Investigation Inspections – 0</p>		
E. Legislation & Regulations	B. Clark, Legislative Liaison	<p><b>Regulations</b> <b>COMAR 10.19.03.08C and 21 C.F.R §1306.13:</b> Regulatory edits:</p> <p>21 C.F.R. § 1306.13 (a) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription, written record of the emergency oral prescription, <b>or in the electronic prescription record.</b> The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall notify the</p>	10.19.03.08 MD regulation less restrictive than federal regulation	

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		<p>prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.</p> <p>COMAR 10.19.03.08C (1) The partial filling of a prescription for a controlled dangerous substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription, and the pharmacist makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.</p> <p><b><u>Revision Summary 10.19.03.08:</u></b> The purpose of this action is to bring Maryland regulations into harmony with federal law. 21 U.S.C. § 829(f) includes requirements for the partial filling of Schedule II substances that are not currently required under Maryland regulations. Specifically, the federal law requires that a partial fill be requested by a patient or prescriber, while Maryland regulations do not. The proposed amendment will cure this discrepancy. There is also a discrepancy related to partial fills in emergency situations. The federal statute requires that, in the event of an emergency partial fill, the remaining portion may be filled “not later than 72 hours after the prescription is issued.” Maryland regulations, on the other hand, require that the remaining portion be filled within 72 hours “of the first partial filling.” Though this difference is minor, it does indicate that the 72 hour period begins to toll at a different time under state regulations than it does under federal law. The regulation will thus be amended to mirror the language of the federal statute.</p> <p><b><u>Legislation</u></b></p>		



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		<p>paperless drug information on their mobile phones or some other electronic device.</p> <p><b><u>Proposed response:</u></b> This practice is not governed by the Maryland Pharmacy Act; however, the practice may be regulated by the US Food and Drug Administration.</p> <p><b><u>Valerie Snyder-Safeway Pharmacy:</u></b> A local pediatrician is asking if my community pharmacy can dispense vaccinations for administration in his physician office. The patients in question are under 9 so we cannot administer the vaccine at the pharmacy. They intend to send prescriptions to our pharmacy for the specific patient that will be receiving the vaccine so it will not be for general "office use". They would like to send us the prescription order, we fill it, the parent picks up the vaccine and brings it to the physician office, and the physician administers the vaccine. Does Maryland pharmacy law allow this type of practice?</p> <p><b><u>Proposed response:</u></b> Yes,</p> <p><b><u>Veronica Kerner-AAMC Ambulatory Pharmacy:</u></b> If you are not billing for any service and thus not subject to the Medicare rules for "incident to" billing, could a pharmacist participate in a collaborative practice agreement from a central location making telephone calls (say hospital clinic of all pharmacists) without the prescriber physician(s) or ANP(s) of the agreement present in the same physical location?</p> <p><b><u>Proposed response:</u></b> Yes, a pharmacist may practice pharmacy independently. The Board does not govern reimbursement.</p> <p><b><u>Steve Bouyoukas-Walgreen Co.</u></b> <b>Steve is recused:</b> 1. Does the MD BOP plan to adopt USP 795 and enforce the standards it lays out?</p>	<p><b>Motion by committee to approve draft response after brief discussion; 2<sup>nd</sup> by D. Ashby</b></p> <p><b>Motion by committee to approve full response; 2<sup>nd</sup> by N. Leikach</b></p> <p><b>Motion by committee to approve draft response with "upgraded" language; 2nd by D. Ashby</b></p>	<p><b>The Board voted to approve this motion</b></p> <p><b>The Board voted to approve this motion</b></p> <p><b>The Board voted to approve this motion</b></p>



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		<p>2. If so, does the MD BOP allow for carve-outs, i.e. the flavoring of a conventionally manufactured/commercially available drug is not subject to the requirements associated with preparation of a compounded non-sterile product?</p> <p><b><u>Proposed response:</u></b> 1. The Board does have the authority to enforce standards of practice with respect to non- sterile compounding. However it has not adopted 795 into its regulations at this time.</p> <p>2. See answer to #1.</p> <p><b><u>Priscilla Bell, Baltimore City Health Department:</u></b> I am in the middle of preparing a Standard Operations Procedure (SOP) for the clinics and there is a Pyxis medication dispenser in the clinics. Can you please provide me with the regulations for who should be responsible for the operation of the Pyxis (the stocking, and monitoring). I would really appreciate any information you can provide.</p> <p><b><u>Proposed response:</u></b> The prescriber under whose authority the drug is being purchased is ultimately responsible for the storage and handling of the drug including Pyxis. For further information contact Maryland Board of Physicians (BBQA).</p>	<p><b>Motion by K. Morgan to approve response #1 and table #2 for review and re-consideration next month</b></p> <p><b>Motion by committee to approve draft response; 2nd by D. Ashby</b></p>	<p><b>The Board voted to approve this motion</b></p> <p><b>The Board voted to approve this motion</b></p>

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B. Licensing Committee	D. Ashby, Chair	<p>1. Review of Pharmacist Applications:</p> <p>a. <b>TR-</b> Via email, a request was sent inquiring about obtaining a pharmacist license by reciprocity. The individual is a foreign graduate and licensed pharmacist in CT. He passed the FPGEE in 2012 and TOEFL. To hold an active license in CT, the FPGEC was not a requirement at that time. His FPGEC application expired in 2017. (NABP policy for the FPGEC, is that the score is valid for five years and an individual must be FPGEC certified in order to apply for the License Transfer application (LTP). He is requesting approval from the MDBOP to grant approval to reactivate his License Transfer application status (NABP/LTP) and background check.</p> <p>This case was reviewed on the August 2019 Licensing Committee agenda.  <u>Committee's Recommendation: Approve until:</u>  <u>1.FPGEE &amp; TOEFL for 1 year</u>  <u>2.Need to be FPGEC certified to be licensed by reciprocity in MD</u></p> <p>b. <b>CLB-</b> The licensee is requesting via email, that the CE hours that she used to reinstate her license on 8/12/2019, be considered for her September 30, 2019 renewal. She states that she will not have adequate time to complete the 30 CE hours in the coming month given other work requirements.</p>	<p>Recommendation by committee to approve extension of FPGEE and TOEFL scores for one year with the consideration that applicant is FPGEC certified for licensure by reciprocity</p> <p>Recommendation by committee to approve waiving September CE requirements</p>	<p>The Board voted to approve this motion</p> <p>The Board voted to approve this motion</p>

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		<p>“When reinstating, a licensee cannot have a license reflecting more than two-years.” Which caused the licensee to have a license for one-month after reinstatement.  <u>Committee’s Recommendation: Approve, Waive CE requirements for September renewal</u></p> <p>2. Review of Pharmacy Intern Applications: NONE</p> <p>3. Review of Pharmacy Technician Applications: NONE</p> <p>4. Review of Distributor Applications: NONE</p> <p>5. Review of Pharmacy Applications:  a. ES- The Board previously denied the pharmacy application for a waiver pharmacy permit in July 2019. The waiver application is being resubmitted for consideration.  <u>Committee’s Recommendation: Approve</u></p> <p>6. Review of Pharmacy Technicians Training Programs: NONE</p> <p>7. Review of Contraception Training Programs: NONE</p> <p>8. New Business:  a. CPE Monitoring with NABP- Bulk purchasing of CPE Monitoring Plus subscriptions for MD license pharmacist and audit capabilities to</p>	<p>Recommendation by committee to approve waiver permit with possible request for further materials</p> <p>Recommendation by committee to deny, 2<sup>nd</sup> from S. Bouyoukas</p>	<p>The Board voted to approve this motion</p> <p>The Board voted to approve this motion</p>
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		<p>reduce operational costs for conducting CPE audits.  The Board would be charged a fee of \$269,520.00.  <u>Committee's Recommendation: Deny</u></p>		
C. Public Relations Committee	E. Yankellow, Chair	Public Relations Committee Update:		
D. Disciplinary	J. Hardesty, Chair	Disciplinary Committee Update		
E. Emergency Preparedness Task Force	N. Leikach, Chair	Emergency Preparedness Task Force Update		
IV. Other Business & FYI	K. Morgan, President			
V. Adjournment	K. Morgan, President	<p>A. The Public Meeting was adjourned.</p> <p>B. K. Morgan convened a Closed Public Session to conduct a medical review committee evaluation of confidential applications.</p> <p>C. The Closed Public Session was adjourned. Immediately thereafter, K. Morgan</p>		

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		<p>convened an Administrative Session for purposes of discussing confidential disciplinary cases.</p> <p>D. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Closed Public Session and the Administrative Session.</p>		